

**PSJ9 Exh 28**



1 formalized process of understanding the  
2 practice to the drug, correct?

3 A. Correct.

4 Q. You would agree with me that  
5 concept is a "know your customer"  
6 concept, correct?

7 A. It's a way of knowing your  
8 customer. It is a way.

9 Q. Okay. Her fourth finding,  
10 "Orders that are highlighted as  
11 suspicious are all investigated. Those  
12 that are cleared from suspicious status  
13 are released. Those that are not are  
14 canceled. At the end of each month, two  
15 reports are submitted to the appropriate  
16 field office of the DEA. The first  
17 report includes those pended orders that  
18 were cleared from suspicious status. The  
19 second report reflects those orders that  
20 were deemed suspicious and canceled."

21 Did you understand that that  
22 was the practice through 2005 for pended  
23 and suspicious orders?

24 A. Yes.

1                   Q.     Did you understand though in  
2     that practice, that she recommended that  
3     suspicious orders be reported immediately  
4     and not at the end of the month. By  
5     reporting them on a monthly basis at the  
6     end of the month was inconsistent with  
7     the Controlled Substances Act  
8     requirements.

9                   MR. McDONALD: Object to the  
10    form.

11                  THE WITNESS: In 2005, I  
12    don't recall if that was  
13    inconsistent with the act.

14    BY MR. MIGLIORI:

15                  Q.     She finds -- she documents  
16    here the requirement, "The registrant  
17    shall inform the field division office of  
18    the administration in this area of  
19    suspicious orders when discovered by the  
20    registrant."

21                  Her recommendation she  
22    writes, "While HSI has been using the  
23    current reporting process for several  
24    years, it is recommended consideration to

1 be given to filing the suspicious order  
2 for those orders not released from  
3 suspicious status to the DEA  
4 immediately."

5 Do you understand that that  
6 was the recommendation then, that  
7 reporting them at month's end was not  
8 consistent with the requirements of the  
9 Controlled Substances Act?

10 A. That was her recommendation.

11 Q. Okay. Fifth finding. "When  
12 an order pends as suspicious, the order  
13 and the customer patterns are reviewed.  
14 If it still remains suspicious, a letter  
15 is sent to the customer requiring an  
16 explanation of the order. A pending  
17 order will not be released without a  
18 return letter from the customer."

19 Will you agree with me that  
20 the methodology at Schein through  
21 September of 2005, and beyond, was, when  
22 an order pended, that a letter was sent  
23 by first class mail to the doctor or the  
24 customer for further information?

1                   to -- to be able to readily review  
2                   the orders for each of these  
3                   criteria.

4                   Whereas, again, the system  
5                   was already in existence many  
6                   years prior to 2008. It may not  
7                   have been computer -- automated,  
8                   but it's still -- it was able to  
9                   review and identify suspicious  
10                  orders.

11          BY MR. MIGLIORI:

12          Q.        Well, we just went  
13                  through -- I don't want to go through  
14                  them again. But we just went through  
15                  Buzzeo's findings in 2005, and it wasn't  
16                  picking up that it needed -- there needed  
17                  to be a new review of how to check orders  
18                  for patterns and frequency, not just  
19                  size. Do you recall that?

20          A.        Yes.

21          Q.        And one of the things this  
22                  new monitoring system will review is,  
23                  among other things, purchasing patterns.  
24          That is a new way of looking at the

1 ordering -- the orders coming into  
2 Schein, according to this document.

3 A. From a systematic approach.

4 Q. From a systematic approach.

5 And from any approach. That there was,  
6 according to Buzzeo in 2005, no  
7 independent review of just pattern in the  
8 system prior to this change.

9 A. In the computer system?

10 Q. Right.

11 A. In the computer system.

12 Q. In the computer system?

13 A. In the computer system.

14 Q. The system was not picking  
15 up changes in pattern or frequency in the  
16 computer system.

17 A. I would agree with that.

18 Q. And this new system was  
19 going to do that.

20 A. In the computer system.

21 Q. In the computer system.

22 And that computer system  
23 didn't get implemented in final process  
24 until October of 2009, according to your

1 says here, when -- the order is DEA and  
2 board of pharmacy are notified by  
3 regulatory affairs.

4 Q. Where?

5 A. This stuff here.

6 Q. So under this system, this,  
7 on the third page?

8 A. On this flowchart.

9 Q. So in 2011, when an order --  
10 I'll go back to Page 2 for a second.  
11 When an order is pended, because of a  
12 deviation in size, frequency or pattern,  
13 by this procedure the DEA isn't notified  
14 immediately as of February of 2011?

15 A. The order is -- is pended  
16 here. It's not deemed to be suspicious.

17 Q. All right. But what we saw  
18 in the early documents that a suspicious  
19 order is one that is a deviation in size,  
20 frequency, and pattern.

21 A. Right.

22 Q. And that once pended, it  
23 needs to be reported, as Buzzeo stated in  
24 2005, it needs to be reported

1 immediately, correct?

2 MR. McDONALD: Object to the  
3 form. Mischaracterizes the  
4 document.

5 BY MR. MIGLIORI:

6 Q. Not -- not at the end of the  
7 month, correct?

8 MR. McDONALD: Object to the  
9 form. Mischaracterizes the  
10 document and the testimony. That  
11 is not what the document said.

17 BY MR. MIGLIORI:

18 Q. I'm going to -- let me give  
19 you a hypothetical so we're not  
20 confusing.

21 If an order is a deviation  
22 in size, it is a pended order in Henry  
23 Schein's system, correct?

24 A. If it's a deviation in size.

1 Q. Yes?

2 A. Yes.

3 Q. An order that is a deviation  
4 in size, by definition under the CSA, is  
5 suspicious, correct?

6 MR. McDONALD: Object to the  
7 form.

8 THE WITNESS: Not  
9 necessarily.

10 BY MR. MIGLIORI:

11 Q. All right. Well, you  
12 actually had a document where you said  
13 exactly that, that we just referred to  
14 earlier.

15 You're saying that a  
16 deviation in size is not a suspicious  
17 order?

18 A. Potential, potentially.

19 Potential. It could be. That's the  
20 review process that we're doing here.

21 Q. So in Schein's system, in  
22 February of 2011, Schein is not reporting  
23 immediately a deviation in size of order  
24 from prior purchasing history to the DEA

1       upon discovery. Is that true?

2           A.       We were reporting suspicious  
3       orders.

4                   Our definition of a  
5       suspicious order, after the review is  
6       conducted and deemed to be suspicious,  
7       that's when it was reported immediately.

8           Q.       So this flowchart is  
9       accurate, that you would not have told  
10      DEA about this until you got to this last  
11      step here of it being --

12       A.       Deemed suspicious.

13       Q.       -- deemed suspicious.

14                   All right. And then it  
15       says, "Notes are placed in the system to  
16       prevent future shipments of controlled  
17       substances to this customer."

18                   Where would that go, where  
19       would that go into the system?

20       A.       That's a verification  
21       function. I don't know where they'd put  
22       that.

23       Q.       Would you know where to find  
24       it if you were asked to consult on a